



EXPRESS MAIL LABEL NO. EV 710327505 US

PATENT APPLICATION

Docket No. 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

In re application of)
)
	Steven D. Jensen, et al.)
)
Serial No.:	09/710,181) Art Unit
) 1616
Filed:	November 10, 2000)
)
Conf. No.:	4245)
)
For:	COMPOSITIONS AND METHODS FOR)
	WHITENING AND DESENSITIZING TEETH)
)
Examiner:	Alton Nathaniel Pryor)
)
Customer No.:	022913)

APPEAL BRIEF

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants Stephen D. Jensen and Dan E. Fischer, D.D.S., previously filed a timely Notice of Appeal from the action of the Primary Examiner in finally rejecting all of the claims in this application. This Appeal Brief is being filed under the provisions of 35 U.S.C. § 134(a) and 37 C.F.R. § 41.37.

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REAL PARTY IN INTEREST

Ultradent Products, Inc. is the real party in interest, as evidenced by the Assignment recorded at Reel 011296, Frames 0368 – 0372.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Pending claims: 41, 42 and 44-87.

Rejected claims: 41, 42 and 44-87.

Allowed claims: none.

Appealed claims: 41, 42 and 44-87.

STATUS OF AMENDMENTS

None filed after Final Rejection.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 41 describes a dental bleaching composition for whitening and desensitizing a person's teeth. Application, p. 5, ll. 1-5. The bleaching composition comprises a dental bleaching agent, potassium nitrate in a range of about 0.01% to about 2% by weight of the dental bleaching composition, and a carrier into which the dental bleaching agent and potassium nitrate are dispersed. *Id.* at p. 5, ll. 5-7, 11-12; p. 8, ll. 18-19. The dental bleaching agent is included in an amount so as to effect bleaching of a person's teeth. *Id.* at p. 10, ll. 4-7. Peroxides used to bleach teeth are known to cause irritation and tooth sensitivity for some people. *Id.* at p. 8, ll. 11-12. Including potassium nitrate in an amount within the narrowly tailored range of about 0.01-2% has been shown, by comparative testing, to unexpectedly provide superior desensitization than bleaching compositions that include a greater amount of potassium nitrate. *Id.* at p. 8, ll. 12-13, 18-22; p. 9, ll. 7-13; p. 27, l. 11 – p. 29, l. 8; Fischer Declaration (Evidence Appendix), ¶¶ 11-17. The fact that including less potassium nitrate, a desensitizing agent, in a dental bleaching composition that also includes a tooth bleaching agent has been found to provide superior desensitization than including more potassium nitrate is counterintuitive, surprising and unexpected. *See* Application, p. 8, ll. 20-22; p. 10, ll. 10-13; p. 12, ll. 7-11.

Claim 59 is similar to claim 41, but recites a narrower concentration range for potassium nitrate of about 0.05% to about 1% by weight of the dental bleaching composition (*i.e.*, the “more preferred” range). *Id.* at p. 8, ll. 19-20; p. 13, ll. 9-10. The narrower concentration range of claim 59 more closely centers around the most preferred concentration of about 0.5% potassium nitrate than the range of claim 41. *See id.* at p. 26, l. 12 – p. 27, l. 9 (Example 2 is the most preferred composition and contains 0.5% potassium nitrate).

Claim 65 is similar to claims 41 and 59, but recites the most preferred concentration of potassium nitrate of about 0.5% by weight of the dental bleaching composition. *Id.* at p. 26, l. 12 – p. 27, l. 9; p. 33, ll. 16-17.

Claims 72, 77 and 81 each recite a method of bleaching and desensitizing a person’s teeth using dental bleaching compositions having amounts of potassium nitrate that vary in the same manner as in claims 41, 59 and 65, respectively. *See id.* at p. 6, ll. 3-12; p. 23, ll. 3-12; p. 24, ll. 17-24.

Claim 86 is similar to claim 41, but further limits the carrier as including a solvent together with a tackifying agent. *Id.* at p. 16, ll. 8-16; p. 18, ll. 8-18. Providing a carrier that includes a solvent together with a tackifying agent yields a sticky gel, which provides superior adhesion of the dental bleaching composition to a person’s teeth. *Id.* at p. 15, l. 12; p. 16, ll. 8-9.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 41, 42 and 44-87 stand rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1-8, 10, 11, and 13-26 of U.S. Patent No. 6,309,625 to Jensen et al. (“Jensen ’625”). Office Action dated August 23, 005, p. 2; Office Action dated April 5, 2005, pp. 3-4. Because insufficient details of this rejection are contained in the August 23, 2005 Office Action, reference is made to the April 5, 2005 Office Action to better understand the actual grounds for the obviousness-type double patent rejection vis-à-vis Jensen ’625. The April 5, 2005 Office Action first reviewed the similarity of the components recited in the claims of the present application and the *disclosure* of Jensen ’625. *Id.* The April 5, 2005 Office Action also alleged that the range of potassium nitrate disclosed in Jensen ’625 (*i.e.*, about 0.1-50%) encompasses the narrow ranges recited in the claims of the present application (*i.e.*, about 0.01-2%, about 0.05-1%, and about 0.5%). *Id.* at p. 4. The April 5, 2005 Office Action acknowledged that comparative data presented by Appellants demonstrates unexpected results when including potassium nitrate in a range of about 0.01-2%. *Id.* (comparative data “suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is

in agreement with Applicant's results."'). The April 5, 2005 Office Action nevertheless maintained the rejection, apparently arguing that the comparative data only pertains to dental bleaching compositions that contain either 10.5% or 15% carbamide peroxide, not other concentrations of peroxide within the claimed range of about 0.5-50%. *Id.* The August 23, 2005 Office Action maintained the previous rejection, but further relies on Examples 7 and 14 of the specification of Jensen '625.

2. Claims 41, 42 and 44-87 stand rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1-23 of U.S. Patent No. 6,306,370 to Jensen et al. ("Jensen '370"). Office Action dated August 23, 2005; Office Action dated April 5, 2005, pp. 4-5. Because insufficient details of this rejection are contained in the August 23, 2005 Office Action, reference is made to the April 5, 2005 Office Action to better understand the grounds for the obviousness-type double patent rejection vis-à-vis Jensen '370. The April 5, 2005 Office Action reviewed the similarity of the components recited in the claims of the present application and the *disclosure* of Jensen '370 and alleged that the range of potassium nitrate disclosed in Jensen '370 (*i.e.*, about 0.1-50%) encompasses the narrow ranges recited in the claims of the present application (*i.e.*, about 0.01-2%, about 0.1-1%, and about 0.5%). *Id.* at p. 5. The April 5, 2005 Office Action acknowledged that comparative data presented by Appellants demonstrates unexpected results when including potassium nitrate in a range of about 0.01-2%. *Id.* (comparative data "suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results.'). The April 5, 2005 Office Action nevertheless maintained the rejection, apparently arguing that the comparative data only pertains to dental bleaching compositions that contain either 10.5% or 15% carbamide peroxide, not other concentrations of peroxide within the claimed range of about 0.5-50%. *Id.* The August 23, 2005 Office Action maintained the previous rejection, but further refers to Examples 7 and 14 of the specification of Jensen '370.

ARGUMENT

I. INCORPORATION OF PREVIOUS ARGUMENTS

Appellants incorporate by reference the arguments showing the claims of the present application are not obvious over the *claims* of Jensen '625 and Jensen '370 set forth in Amendment "I" and Response filed June 13, 2005 (pp. 12-17) and Amendment "H" and Response filed December 14, 2004 (p. 19).

II. COMPARATIVE DATA SUBMITTED BY APPLICANTS DEMONSTRATES THAT INCLUDING POTASSIUM NITRATE WITHIN THE CLAIMED RANGES PROVIDES UNEXPECTED RESULTS, WHICH REBUTS THE ALLEGATION THAT THE CLAIMED DENTAL COMPOSITIONS ARE PRIMA FACIE OBVIOUS OVER THE CLAIMS OF JENSEN '625 AND JENSEN '370

A. Comparative Data Set Forth in the Application and the Declaration of Dan E. Fischer, D.D.S. Filed June 24, 2001 Demonstrate Unexpected Results With Respect to Dental Bleaching Compositions that Contain Potassium Nitrate Within the Claimed Ranges, Namely Superior Desensitizing Capabilities

Potassium nitrate is a well-known tooth desensitizing agent that is effective in relieving pain associated with sensitive teeth. Fischer Declaration, ¶ 7 (Evidence Appendix). Potassium nitrate has been used within desensitizing gels and dentrifices (*i.e.*, toothpaste) to relieve pain associated with sensitive teeth. *Id.* at ¶ 8; Application, p. 10, ll. 14-18. The standard concentration of potassium nitrate within desensitizing compositions is about 3-5% by weight. Fischer Declaration, ¶ 9. Desensitizing toothpaste compositions can include up to 10% by weight potassium nitrate. Application, p. 10, ll. 15-17. Since conventional dental desensitizing compositions typically include at least 3% potassium nitrate, there is no reason to doubt that such concentrations are effective in relieving pain associated with sensitive teeth. Indeed, when used alone, in the absence of a peroxide dental bleaching agent, 3% or more potassium nitrate is known to be effective in treating tooth sensitivity. *See id.* at p. 10, ll. 14-22; Fischer Declaration, ¶¶ 7-9, 11.

Because potassium nitrate is known to desensitize teeth, it stands to reason that including more potassium nitrate should provide greater relief to those who suffer from sensitive teeth, while including less should provide a lesser amount of such relief.¹ Moreover, because potassium nitrate is known to be effective in treating sensitize teeth at concentrations of 3% and above, one of skill in the art would not expect potassium nitrate, when included in a standard amount of 3% to cause greater tooth and oral sensitivity than not including *any*, or even a lesser quantity of, potassium nitrate. Yet that is exactly what was surprisingly and unexpectedly found when using potassium nitrate in combination with a peroxide dental bleaching agent. Fischer

¹ It is well-known, however, that many substances have diminishing returns. Therefore, one of skill in the art might assume there is an amount of potassium nitrate that provides maximum tooth desensitization and that including more potassium nitrate beyond that amount will not provide any significant increase in the desensitization effect.

Declaration, ¶¶ 14-17. In the case of dental bleaching compositions that contain a peroxide tooth bleaching agent and potassium nitrate as a tooth desensitizing agent, comparative testing has shown that the optimal quantity of potassium nitrate is only about 0.5% by weight of the composition. Application, p. 26, l. 12 – p. 29, l. 8; Fischer Declaration, ¶¶ 11-17. Dental bleaching compositions that include 0.5% potassium nitrate have been shown by comparative testing to provide superior tooth desensitization than bleaching compositions that include 3% potassium nitrate. Fischer Declaration, ¶ 17.

This is entirely counterintuitive in view of the known fact that potassium nitrate is known to be an effective tooth desensitizing agent when included in amounts of 3% or greater in compositions that do not include a peroxide bleaching agent. *See id.* at ¶¶ 16-17. Because potassium nitrate is a known desensitizing agent, one of skill in the art would have expected 3% potassium nitrate to be *more* effective in treating tooth sensitivity than only 0.5%, an amount that is only 1/6 as much as 3%. The fact that including *less* potassium nitrate was found to be *more* effective in treating tooth sensitivity than including more potassium nitrate is a surprising and unexpected result.

Even more unexpected and surprising was the finding in the comparative study that including 3% potassium nitrate within a dental bleaching composition was, in some cases, worse than including no potassium nitrate at all. Including 3% potassium nitrate within a dental bleaching composition containing a peroxide bleaching agent actually caused *increased* tooth sensitivity, on average, to hot or cold, as well as greater tongue sensitivity, compared to a bleaching composition containing *no* potassium nitrate. Fischer ¶¶ 13-14. Thus, when included within a dental bleaching composition in an amount of 3% together with a dental bleaching agent, potassium nitrate ceases to act as a tooth desensitizing agent for at least some people suffering from tooth and other oral sensitivities caused by the peroxide dental bleaching agent. *Id.* at ¶ 15. That is also surprising, unexpected and entirely counterintuitive given the fact that potassium nitrate is known to be effective in treating tooth sensitivity when included in amounts of 3% or greater in compositions that do not include a dental bleaching agent. *Id.* at ¶¶ 7-8, 16.

B. The Claims as Presented for Appeal are Narrowly Tailored With Respect to Both the Amount of Dental Bleaching Agent and Potassium Nitrate Based on the Results of the Comparative Study

Each of the claims on appeal is limited to potassium nitrate within very narrowly tailored concentration ranges that were determined and extrapolated from the results of the comparative study. The narrowly tailored ranges for potassium nitrate are designed to at least partially remedy or offset tooth sensitivity that may be caused by the peroxide bleaching agent included in a tooth bleaching amount. As discussed more fully below, the Examiner agreed in the April 5, 2005 Office Action that even the broadest claimed range of about 0.01-2% potassium nitrate shows “unexpected results” based on the comparative study. April 5, 2005 Office Action, pp. 4-5 (comparative data “suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant’s results.”).

The claims are also limited to an amount of dental bleaching agent that has “a tooth bleaching effect when contacted with a person’s teeth”. It stands to reason that including an amount of dental bleaching agent that has a tooth bleaching effect is more likely to cause tooth sensitivity than including an amount that has no tooth bleaching effect. Of course, not all persons experience tooth sensitivity.

The comparative study further showed that varying the amount of tooth bleaching agent had virtually no effect on the amount of tooth and other oral sensitivity experienced by the individuals in the study. *See* Application, p. 27, l. 11 – p. 29, l. 8; Fischer Declaration, ¶¶ 12-14. For those compositions that contained 3% potassium nitrate, increasing the concentration of dental bleaching agent from 10% to 15% (an increase of 50%, or 5 full percentage points) had little, if any, effect on the incidence of sensitivity. *See* Application, p. 27, l. 11 – p. 29, l. 8; Fischer Declaration, ¶¶ 12-14 (the results for compositions B-D do not vary much, if at all). In contrast, varying the amount of potassium nitrate had an enormous effect on the incidence of sensitivity, as shown by comparing the results for compositions A and E with those for compositions B-D. *See* Application, p. 27, l. 11 – p. 29, l. 8; Fischer Declaration, ¶¶ 12-14. Because altering the concentration of potassium nitrate was shown by the comparative study to dramatically alter the incidence of sensitivity, while variations in the concentration of the dental bleaching agent had little or no effect on sensitivity, it is clear that the concentration of potassium nitrate, not the dental bleaching agent, is the result-effective variable identified by the comparative study. These results are consistent with the specification, which identifies

potassium nitrate, not the dental bleaching agent, as the result-effective variable. *See* Application, p. 8, ll. 7-8; p. 9, l. 24 – p. 10, l. 7; p. 12, ll. 7-11.

Because the concentration of potassium nitrate, not the concentration of the dental bleaching agent, is the result-effective variable that was found to correlate with the incidence of tooth sensitivity, it is far more important for the claims to recite a concentration range for the potassium nitrate that is narrowly tailored than the concentration of the dental bleaching agent. Nevertheless, the fact that the amount of the dental bleaching agent recited in the claims is the “preferred” concentration disclosed in the Application (p. 18, l. 24 – p. 19, l. 1), and is further limited by the qualifying phrase “so as to have a tooth bleaching effect when contacted with a person’s teeth”, the amount of dental bleaching agent recited in the claims is sufficiently narrow and is symmetrical with the amount of potassium nitrate, which is also the “preferred” range (p. 13, l. 8). Thus, the statements in the April 5, 2005 Office Action implying that the amount of dental bleaching agent recited in the claims is too broad, notwithstanding the admission by the examiner that the claimed potassium nitrate range shows “unexpected results”, is erroneous in light of the results of the comparative study and the specification, both of which identify the concentration of potassium nitrate as the result-effective variable.

In short, the claims presented for appeal are sufficiently narrowly tailored with respect to both the concentration of potassium nitrate and the dental bleaching agent based on their relative effects on changing the incidence of tooth sensitivity according to the comparative study.

C. Neither the Claims of Jensen '625 nor the Claims of Jensen '370 Teach or Suggest Dental Bleaching Compositions that Include Potassium Nitrate Within the Narrowly Tailored Ranges Recited in the Claims Presented for Appeal

It is the claims, not the specification, of a commonly owned patent to which subsequent claims must be compared when determining whether there is obviousness-type double patenting. The specification is mainly used to construe the meaning of ambiguous or unclear terms found in the claims. The specification must be considered for all that it teaches, including those portions that lead away from claims of the application at issue. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). An Examiner may not pick and choose only those teachings that support the rejection while ignoring other sections that lead away from the claims at issue.

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized “that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim,” but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

MPEP § 804 (emphasis added). In view of MPEP § 804, it is clear that the specifications of the Jensen '625 and '370 patents may be “examined and considered” but only those portions of the disclosure that support what is “claimed” in the patent.

Appellants acknowledge that the broad ranges for potassium nitrate recited in the claims of Jensen '625 and Jensen '370 may, in some cases, overlap at least a portion of the narrow ranges recited in the claims on appeal. That has never been disputed. It is for that reason that Appellants presented comparative data showing that including a relatively small amount of potassium nitrate in combination with a dental bleaching agent used to bleach teeth surprisingly and unexpectedly resulted in a superior desensitization effect compared to using a greater amount of potassium nitrate within the ranges recited in the claims of Jensen '625 and Jensen '370. The broad concentration ranges for potassium nitrate recited in the claims of Jensen '625 and Jensen '370 do not teach or suggest to one of skill in the art the desirability of including a relatively small quantity of potassium nitrate within the narrowly tailored ranges recited in the claims on appeal. The comparative study, because it demonstrates surprising and unexpected results for the narrow claimed, ranges, is sufficient to rebut the allegation that the claims are *prima facie* obvious over the claims of Jensen '625 and Jensen '370.

According to MPEP § 804:

A double patenting rejection of the obviousness-type is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103” except that the patent principally underlying the double patenting rejection is not considered prior art. *In Re Braithwaite* F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination. *In Re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1999); *In Re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

MPEP § 804 goes on to state that the factual inquiry set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that is applied for determining obviousness under 35 U.S.C. § 103 is employed when making an obviousness-type double patenting analysis. One of the factors includes “evaluat[ing] any objective indicia of nonobviousness”. The comparative study is objective evidence that the claims are unobvious over the claims of Jensen ’625 and Jensen ’370, and must be considered according to MPEP § 804.

The comparative study is valid for even the broadest range of about 0.01-2% potassium nitrate (which was admitted by the Examiner in the April 5, 2005 Office Action). Both the MPEP and case law provide the following rule:

[T]he unobviousness of a broader claimed range, can in certain instances, be proven by a narrower range of data. Often, one having ordinary skill in the art may be able to ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value thereof

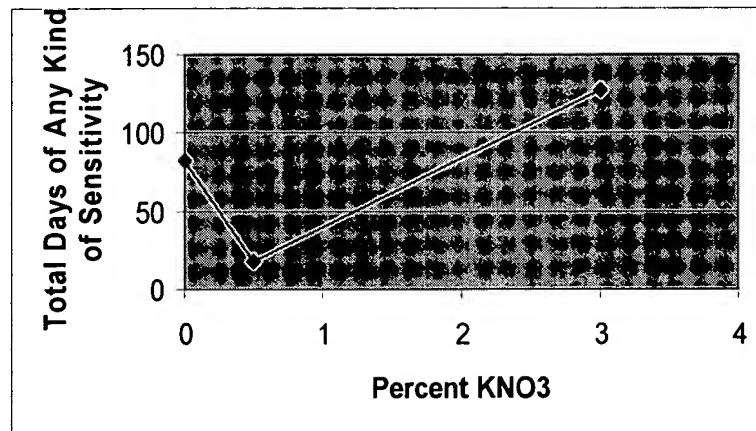
In re Kollman, 595 F.2d 48, 56 (CCPA 1979). The MPEP recognizes this reading of *Kollman*:

The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof.

MPEP § 716.02(d) (citing *Kollman*).

Here, there are essentially three data points (0%, 0.5%, 3%), one of which is within the claimed ranges (about 0.01%-2%, about 0.05%-1%, and about 0.5%) and two of which are outside. However, one of ordinary skill in the art can definitely “ascertain a trend in the

exemplified data which would allow him to reasonably extend the probative value thereof.” *Kollman*, 595 F.2d at 56. The chart below shows the trend:



There are several “trends” that can be discerned from this data. First, sensitivity *increases* from 0.5% potassium nitrate to 3% potassium nitrate. Second, sensitivity at 0% potassium nitrate is *lower than* sensitivity at 3% potassium nitrate. Both of these are “unexpected results.” Third, sensitivity decreases from 0% potassium nitrate to 0.5% potassium nitrate. This is not an “unexpected result.”

The “probative value” of the data can be “reasonably extend[ed]” to observe that including 2% potassium nitrate within a dental bleaching composition would be reasonably expected to provide about the same level of sensitivity as no potassium nitrate at all. Therefore, the data also reasonably implies that some range of potassium nitrate more than 0% and less than about 2% will decrease sensitivity compared to including either no potassium nitrate or 3% potassium nitrate. That is an unexpected result because it would be expected that 3% potassium nitrate should *decrease* sensitivity compared to values between 0% and 2% (*i.e.*, including more desensitizing agent should desensitize more, not less, than including about 0.01% to about 2% of the same component). In fact, the comparative study and trends reasonably deduced from the study show the counterintuitive result that including 3% potassium nitrate was worse in desensitizing teeth than including less or even no potassium nitrate. That is clearly unexpected. The foregoing analysis demonstrates that, at the very least, the data and “reasonable exten[sions]” thereof show unexpected results for the entirety of the claimed ranges.

In contrast to the narrow ranges recited in the claims on appeal, the claims of Jensen '625 and Jensen '370 recite very broad ranges that in no way point to the narrow ranges recited in the subject claims. The Federal Circuit has held that where the prior art (in this case, the ranges recited in the claims of Jensen '625 and Jensen '370 and the totality of teachings in the disclosure) gives no indication of which parameters are critical and no direction as to which of many possible choices is likely to be successful, the fact that the claimed invention falls within the scope of possible combinations taught (or claimed) in a cited reference does not render the claim unpatentably obvious. *In re O'Farrell*, 853 F.2d 894, 2 USPQ 2d 1624 (Fed. Cir. 1988). Thus, unless the *claims* of Jensen '625 and Jensen '370 in some way point to the critical nature of narrow ranges recited in the claims on appeal, particularly in light of the unexpected results that are obtained when including an amount of potassium nitrate within the claimed ranges in combination with a dental bleaching agent, the claims on appeal are unobvious over the claims of Jensen '625 and Jensen '370 as a matter of law following the rule articulated by the Federal Circuit in *In re O'Farrell*.

Only claims 2, 3 and 15 of Jensen '625 recite any concentration range for potassium nitrate. Claims 2 and 15 each recite a concentration range for potassium nitrate of "about 0.1% to about 50%". This range is so broad that about 96% of the possible concentration values lie outside the scope of the broadest range in the appealed claims (about 0.01-2%) (*i.e.*, values greater than about 2% up to about 50% constitute about 96% of the range). About 98% of the possible concentration values of the range of about 0.1-50% lie outside of the intermediate range of about 0.05-1% (*i.e.*, values greater than about 1% up to about 50% constitute about 98% of the range). About 99% of the possible concentration values of the range of about 0.1-50% lie outside of the smallest range of about 0.5% (*i.e.*, values greater than about 0.5% up to about 50% constitute about 99% of the range). Because 96%, 98% and 99% of the possible concentration values of the range of about 0.1-50% lie entirely outside the broad, intermediate, and narrow ranges recited in the claims on appeal, respectively, the range of about 0.1-50% in no way points to or suggests the criticality of including an amount of potassium nitrate within the narrowly tailored ranges on appeal (*i.e.*, about 0.01-2%, about 0.05-1%, or about 0.5%). On the other hand, claim 3 recites a range of "about 3% to about 10% by weight" potassium nitrate, which is entirely outside the three ranges presented for appeal. Claim 3 likewise fails to indicate the criticality of the claimed ranges on appeal.

Only claims 1, 2, 14 and 16 of Jensen '370 recite a concentration range for potassium nitrate. Claim 1 recites "at least about 0.1% by weight" potassium nitrate but no upper limit. The analysis given above with respect to the range of about 0.1-50% recited in Jensen '625 applies to claim 1 of Jensen '370, except that claim 1 of Jensen '370 is even broader and less suggestive of the claimed ranges on appeal. Claim 2 of Jensen '370 recites a range of "about 1% to about 7%" potassium nitrate. A large majority of the values within this range (about 71%) fall outside the broadest claimed range of about 0.01-2% on appeal. Moreover, about half of the range of about 0.01-2% is itself outside of, and therefore excluded, by the range of about 1-7%, including the most preferred amount of 0.5% potassium nitrate. The intermediate range of about 0.05-1% is almost entirely outside the range of claim 2, and the narrow range of about 0.5% is entirely outside this range. Finally, about 80%, 90% and 95% of the values within the range of about 0.1-10% recited in claims 14 and 16 are outside the ranges of about 0.01-2%, 0.05-1%, and about 0.5% in the claims presented for appeal.

In view of the foregoing, none of the claims of Jensen '625 or Jensen '370 point to or give any hint as to the criticality of including potassium nitrate in an amount within the narrowly tailored ranges within the claims on appeal, as required by the Federal Circuit in *In re O'Farrell*. For this reason, Appellants submit that the claims on appeal are unobvious over the *claims* of both Jensen '625 and Jensen '370.

While the specifications of Jensen '625 and Jensen '370 may be consulted with regard to the claimed ranges discussed above, they do not provide any more direction than the claims themselves relative to the narrowly tailored ranges within the claims on appeal. Both Jensen '625 and Jensen '370 teach that potassium nitrate is "preferably" included in a range of about 0.1-50% by weight, "more preferably" in a range of about 1-25%, and "most preferably" in a range of about 3-10% by weight. Jensen '625, col. 6, ll. 43-49; Jensen '370, col. 6, ll. 53-59. The fact that the "most preferred" concentration range for potassium nitrate taught in Jensen '625 and Jensen '370 (*i.e.*, about 3-10%) is entirely outside the narrowly tailored ranges in the claims presented for appeal teaches away from the claimed ranges on appeal. Moreover, the *minimum* amount of potassium nitrate within the "most preferred" range of about 3-10% was shown by comparative testing to cause *increased* sensitivity in some people. Presented with the clear teachings in Jensen '625 and Jensen '370 regarding what amount of potassium nitrate is "most preferred", one of skill in the art would not have selected an amount of potassium nitrate in a range of about 0.01-2%, let alone about 0.05-1%, and especially not about 0.5%, as recited in the

claims on appeal. One would expect the best desensitizing to occur by including about 3-10% potassium nitrate according to the clear teachings of Jensen '625 and Jensen '370, not by including an amount of potassium nitrate within ranges of about 0.01-2%, about 0.05-1%, or about 0.5%. This is consistent with the view that the *claims* of the Jensen '625 and Jensen '370 neither teach nor suggest the narrowly tailored concentration ranges within the claims for potassium nitrate on appeal.

D. The Examples of Jensen '625 and Jensen '370 are Consistent With the Broad Concentration Ranges for Potassium Nitrate in both the Claims and Disclosures of Jensen '625 and Jensen '370

The latest Office Action attempts to circumvent the clear teachings in Jensen '625 and Jensen '370 that support the view that the *claims* of Jensen '625 and Jensen '370 lead away from the ranges for potassium nitrate on appeal by referring to Examples 7 and 14 of Jensen '625 and Jensen '370. First of all, Examples 7 and 14 do not claim to include a “preferred” amount of potassium nitrate. Second, they are merely prophetic examples. Jensen '625, col. 16, ll. 41-60; col. 18, l. 52 – col. 19, l. 3; Jensen '370, col. 16, ll. 43-62; col. 18, l. 52 – col. 19, l. 3. All the working examples that were actually made contained at least 3% potassium nitrate. Jensen '625, col. 14, l. 16 – col. 15, l. 13; Jensen '370, col. 14, l. 26 – col. 15, l. 18. Third, the amount of potassium nitrate contained in the composition of Example 14 (*i.e.*, 2.5%) is entirely outside all the ranges recited in the claims on appeal (*i.e.*, about 0.01-2%, about 0.05-1% and about 0.5%). Jensen '625, col. 18, l. 62; Jensen '370, col. 18, l. 62. Example 14 therefore leads away from each of the narrowly tailored ranges recited in the appealed claims. Finally, Example 7 is incomprehensible, and the composition disclosed therein impossible to reproduce, because the amounts of all the recited components add up to 120%, not 100% as in all the other examples. Jensen '625, col. 14, ll. 49-56; Jensen '370, col. 14, ll. 51-58.

Example 7 must be understood for all that it teaches, including the confusion that one of skill in the art would have in trying to manufacture a composition in which all the ingredients added up to more than 100% (*i.e.*, 120%), when determining what relevance it has, if any, as to whether the *claims* of Jensen '625 and Jensen '370 render the narrowly tailored ranges on appeal legally obvious. To say that one of skill in the art should ignore the unresolvable confusion imparted by disclosing ingredients that add up to 120%, but focus only on the amount of potassium nitrate in Example 7 (*i.e.*, 1.0%), would be clearly based on impermissible hindsight.

Nothing else in the Jensen '625 and '370 patents points to the desirability of including 1.0%, rather than 3% or more, potassium nitrate. In any event, nothing in Example 7 limits the broad scope of the *claims* of Jensen '625 and Jensen '370. As discussed above, the overwhelming majority of values within the ranges for potassium nitrate recited in the claims of Jensen '625 and Jensen '370 fall outside the narrowly tailored ranges of the claims on appeal. Jensen '625 and Jensen '370 clearly teach that the “most preferred” amount of potassium nitrate is in a range of about 3-10%. Thus, the amount of potassium nitrate in Example 7, even if it had any meaning in light of the fact that the components inexplicably add up to 120%, would likely have been viewed as an aberration by one of skill in the art in light of the totality of teachings contained in Jensen '625 and Jensen '370. The fact that Example 7 is “prophetic” would lead one of skill in the art to conclude that it was included merely to show an example at the lower end of the claimed ranges. Example 7 would not have been understood as somehow pointing to an amount of potassium nitrate (*i.e.* 0.5%) that has now been shown, by comparative testing, to surprisingly and unexpectedly provide *superior* desensitization compared to including 3% potassium nitrate, which is the lower end of the “most preferred” range in Jensen '625 and Jensen '370.

In view of the foregoing, Appellants maintain that the *claims* of Jensen '625 and Jensen '370, particularly in light of the totality of teachings contained in their respective specifications, do not point to or suggest the critical nature of including an amount of potassium nitrate within the ranges recited in the claims on appeal.

E. The Examiner Has Agreed That the Comparative Data Demonstrates Unexpected Results for Dental Bleaching Compositions that Contain Potassium Nitrate Within the Claimed Ranges

The Examiner clearly stated in several Office Actions that he agrees that comparative data presented by Appellants shows “unexpected results” for even the broadest claimed range for potassium nitrate. The most recent pronouncement of this important admission is contained in the most recent Office Action (April 5, 2005) that actually articulates grounds for rejecting the claims on appeal under the judicially created doctrine of obviousness-type double patenting relative to the claims of Jensen '625 and Jensen '370. The latest Office Action states insufficient grounds for maintaining the obviousness-type double patenting rejections but implicitly relies on the grounds recited in the April 5, 2005 Office. Moreover, the latest Office Action does not rescind the previous view by the Examiner that the comparative data shows

“unexpected results”, but merely relies (albeit erroneously, as discussed above) on Examples 7 and 14 in maintaining the rejection.

As stated in the April 5, 2005 Office Action:

Applicants point out in a declaration and a working example that 10.5% and 15% carbamide [peroxide] plus 0.5% potassium nitrate yields unexpected data. Applicant also refers Examiner to non-working examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. Examiner is in agreement with Applicant's results. However, Examiner argues that Applicant does not provide ample results supporting a peroxide amount ranging from 0.5-50%.

April 5, 2005 Office Action, pp. 4-5 (emphasis added). Thus, the Examiner admitted that the narrowly tailored ranges for potassium nitrate do, in fact, “yield[] unexpected results”. The Examiner only maintained the rejection on the grounds that the comparative study does not support the range of peroxide bleaching agent within the claims. However, as discussed above, it is the amount of potassium nitrate, not the amount of dental bleaching agent, that is the result-effective variable, as shown by the comparative study (*i.e.*, varying the amount of dental bleaching agent by 50%, or 5 percentage points, had virtually no effect on tooth sensitivity, while varying the amount of potassium nitrate had an enormous effect). Thus, the grounds articulated for maintaining the rejection in the last two office actions are legally insufficient to maintain the rejection on appeal.

In short, Appellants maintain that the August 23, 2005 Office Action, even if combined with the April 5, 2005 Office Action, fails to articulate sufficient grounds for maintaining the obviousness-type double patenting rejection relative to the claims of Jensen '625 and Jensen '370. Neither provides any evidence or reasoning rebutting the objective evidence of unexpected results. Both rely on extraneous factors that have nothing to do with whether the narrowly tailored ranges recited in the claims on appeal (*i.e.*, about 0.01-2%, about 0.05-1%, and about 0.5%) are obvious over the broad ranges for potassium nitrate recited in the *claims* of Jensen '625 and Jensen '370.

PRAYER FOR RELIEF

In view of the foregoing, Appellants respectfully request the Board to vacate the final rejection and order the Examiner to allow each of the claims on appeal.

CLAIMS APPENDIX

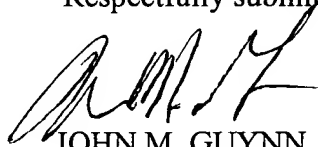
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EVIDENCE APPENDIX

The Declaration of Dan E. Fischer, DDS under 37 C.F.R. §§ 1.132, previously filed and made of record together with Preliminary Amendment "A" on June 25, 2001, is attached hereto, after the Claims Appendix.

Dated this 13th day of January 2006.

Respectfully submitted,



JOHN M. GYNN

Registration No. 36,153

Attorney for Applicant

Customer No. 022913

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CLAIMS APPENDIX

Claims 1-40 (Cancelled)

41. A dental bleaching composition for bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.

42. A dental bleaching composition as defined in claim 41, said dental bleaching agent comprising at least one of hydrogen peroxide, carbamide peroxide, sodium perborate, benzoyl peroxide, or glycerol peroxide.

43. (Cancelled)

44. A dental bleaching composition as defined in claim 41, wherein said dental bleaching agent is included in a range of about 1% to about 30% by weight of the dental bleaching composition.

45. A dental bleaching composition as defined in claim 41, wherein said dental bleaching agent is included in a range of about 3% to about 20% by weight of the dental bleaching composition.

(46. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate has a concentration of about 0.5% by weight of the dental bleaching composition.

47. A dental bleaching composition as defined in claim 41, said carrier comprising a polyol.

48. A dental bleaching composition as defined in claim 47, said polyol comprising at least one of glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, erythritol, sorbitol, or mannitol.

49. A dental bleaching composition as defined in claim 47, said carrier further comprising a tackifying agent.

50. A dental bleaching composition as defined in claim 49, said tackifying agent comprising at least one of carboxypolymethylene, a gum, or a protein.

51. A dental bleaching composition as defined in claim 41, said carrier comprising water.

52. A dental bleaching composition as defined in claim 41, further comprising an antimicrobial agent that is at least one of chlorhexidine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methyl benzoate, or propyl benzoate.

53. A dental bleaching composition as defined in claim 41, further comprising an anticariogenic agent that is at least one of sodium monofluorophosphate, sodium fluoride, or stannous fluoride.

54. A dental bleaching composition as defined in claim 41, further comprising at least one bleaching agent stabilizer that is at least one of EDTA, a salt of EDTA, adipic acid, succinic acid, citric acid, a nitrate of tin, or a phosphate of tin.

55. A dental bleaching composition as defined in claim 41, wherein the dental bleaching composition is free of abrasives.

56. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate reduces sensitivity to at least one of hot or cold.

57. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate reduces at least one of gum, tongue, or throat sensitivity.

58. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate further enhances whitening of teeth by said dental bleaching agent.

59. A dental bleaching composition for bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition so as to result in reduced sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is passively maintained in contact with a person's teeth for at least about 15 minutes without brushing or scrubbing; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.

60. A dental bleaching composition as defined in claim 59, said dental bleaching agent comprising at least one of hydrogen peroxide or carbamide peroxide.

61. A dental bleaching composition as defined in claim 59, wherein said potassium nitrate has a concentration of about 0.5% by weight of the dental bleaching composition.

62. A dental bleaching composition as defined in claim 59, said carrier comprising a polyol and a tackifying agent.

63. A dental bleaching composition as defined in claim 59, further comprising at least one of an antimicrobial agent, an anticariogenic agent, or a bleaching agent stabilizer.

64. A dental bleaching composition as defined in claim 59, wherein the dental bleaching composition is free of abrasives.

65. A dental bleaching composition for bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in an amount of about 0.5% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.

66. A dental bleaching composition as defined in claim 65, said dental bleaching agent comprising at least one of hydrogen peroxide or carbamide peroxide.

67. A dental bleaching composition as defined in claim 65, said carrier comprising a polyol and a tackifying agent.

68. A dental bleaching composition as defined in claim 65, said carrier comprising water.

69. A dental bleaching composition as defined in claim 65, wherein the dental bleaching composition is free of abrasives.

70. A dental bleaching composition as defined in claim 65, wherein said potassium nitrate reduces sensitivity to at least one of hot or cold.

71. A dental bleaching composition as defined in claim 65, wherein said potassium nitrate reduces at least one of gum, tongue, or throat sensitivity.

72. A method for bleaching and desensitizing a person's teeth, comprising:
providing a dental bleaching composition comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed; and

contacting the person's teeth with said dental bleaching composition for a time sufficient to bleach teeth,

said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

73. A method as defined in claim 72, wherein contacting the person's teeth with said dental bleaching composition further comprises:

introducing a quantity of said dental bleaching composition into a dental tray; and
placing the dental tray over the person's teeth in order for the dental bleaching composition to contact the person's teeth for the time sufficient to bleach teeth.

74. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 15 minutes.

75. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

76. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

77. A method for bleaching and desensitizing a person's teeth, comprising:
providing a dental bleaching composition comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed; and

contacting the person's teeth with said dental bleaching composition for at least about 15 minutes without scrubbing or brushing,

said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

78. A method as defined in claim 77, wherein contacting the person's teeth with said dental bleaching composition further comprises:

introducing a quantity of said dental bleaching composition into a dental tray; and

placing the dental tray over the person's teeth for at least about 15 minutes in order for the dental bleaching composition to contact the person's teeth.

79. A method as defined in claim 78, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

80. A method as defined in claim 78, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

81. A method for bleaching and desensitizing a person's teeth, comprising:
providing a dental bleaching composition comprising:
a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;
potassium nitrate in an amount of about 0.5% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and
a carrier into which said dental bleaching agent and potassium nitrate are dispersed; and
contacting the person's teeth with said dental bleaching composition for a desired time period,
said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

82. A method as defined in claim 81, wherein contacting the person's teeth with said dental bleaching composition further comprises:
introducing a quantity of said dental bleaching composition into a dental tray; and
placing the dental tray over the person's teeth in order for the dental bleaching composition to contact the person's teeth for the time sufficient to bleach teeth.

83. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 15 minutes.

84. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

85. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

86. A dental bleaching composition for bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of about 0.5% to about 50% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, said carrier including a solvent together with a tackifying agent.

87. A dental bleaching composition as defined in claim 86, wherein said tackifying agent is selected from the group comprising carboxypolymethylene, polyacrylic acid copolymers, gums, polyethylene oxides, proteins, and mixtures thereof.

Claims 88-90 (Cancelled)

EVIDENCE APPENDIX



EXPRESS MAIL LABEL NO. EL813291105US

PATENT APPLICATION
Docket No: 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Steven D. Jensen and Dan E. Fischer, DDS

Serial No. 09/710,181

Conf. No. 4245

Filed: November 10, 2000

For: COMPOSITIONS AND METHODS FOR
WHITENING AND DESENSITIZING TEETH

Examiner: Raj Bawa, Ph.D.

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DECLARATION UNDER 37 C.F.R. § 1.132
OF DAN E. FISCHER, DDS

The Assistant Commissioner of Patents
and Trademarks
Washington, D. C. 20231

Sir:

I, Dan E. Fischer, DDS, declare as follows:

1. I am one of the named co-inventors of the subject matter disclosed and claimed in the above-identified application, and I am personally knowledgeable of the facts stated herein.
2. Steven D. Jensen is the other named co-inventor of the subject matter disclosed and claimed in the above-identified application.
3. The above-identified application has been assigned to Ultradent Products, Inc. ("Ultradent"), located at 505 West, 10200 South in South Jordan, Utah.

4. The subject matter claimed in the above-identified application is the result of a joint effort between me and Steven D. Jensen.

5. I obtained a doctorate of dental surgery from Loma Linda University, located in Loma Linda, California, in 1974, am currently the president of Ultradent, and continue to practice dentistry in addition to my duties as President of Ultradent, therefore making me knowledgeable in the field of dentistry.

6. The above-identified application discloses and claims desensitizing dental bleaching compositions that comprise a dental bleaching agent, such as carbamide peroxide, and potassium nitrate as a desensitizing agent, both of which are dispersed in an appropriate carrier.

7. Potassium nitrate is known to be an effective desensitizing agent for teeth, as described and claimed in U.S. Patent Nos. 5,851,512 and 5,855,870, both of which are assigned to Ultradent Products, Inc. and which name Steven D. Jensen and myself as co-inventors (Mr. Jensen having been added as a co-inventor after issuance).

8. A desensitizing dental composition containing 3% by weight potassium nitrate, used to alleviate sensitivity associated with home-use dental bleaching compositions, and covered by U.S. Patent Nos. 5,851,512 and 5,855,870, is available from Ultradent Products, Inc. under the trade name ULTRA EZ.

9. It is my understanding, as one knowledgeable in the field of dentistry, that the standard concentration of potassium nitrate within desensitizing dental compositions is about 3-5% by weight.

10. Subsequent to the filing of U.S. Patent Nos. 5,851,512 and 5,855,870, it was discovered that potassium nitrate can, in some cases, when included within a dental bleaching composition in certain concentrations, also enhance the whitening ability of a dental bleaching composition compared to bleaching compositions that do not include potassium nitrate, as described

in U.S. application Serial No. 09/494,113, filed January 31, 2000, now abandoned, in addition to providing a desensitizing effect.

11. Although it is and has been customary to include at least 3% potassium nitrate within desensitizing dental compositions, we discovered, by means of an extensive comparative study summarized in the above-identified application, that potassium nitrate, when included within a dental bleaching composition at concentration of only 0.5% by weight, unexpectedly and surprisingly provides significantly higher degrees of both desensitization and whitening compared to compositions that include either 3% potassium nitrate or no potassium nitrate.

12. As set forth at page 26, line 1, through page 29, line 4, of the above-identified application, five (5) dental bleaching compositions (identified as compositions A-E, respectively) having the following amounts of carbamide peroxide and potassium nitrate were prepared and comparatively tested:

<u>Composition</u>	<u>Carbamide Peroxide</u>	<u>KNO₃</u>
A	10%	0%
B	10%	3%
C	10%	3%
D	15%	3%
E	10.5%	0.5%

13. The results of the comparative study were summarized in the following table found at page 28, lines 1-17, of the above-identified application, with a description of what is meant by each column of data provided beneath the table:

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

14. As indicated by the data set forth in ¶13 above, the comparative study also surprisingly and unexpectedly indicated that potassium nitrate, when included in a concentration of 3% by weight within dental bleaching compositions having 10% or 15% by weight carbamide peroxide (compositions B-D), actually caused *increased sensitivity*, on average, to hot or cold, as well as greater tongue sensitivity, compared to composition A, which included 10% carbamide peroxide and *no* potassium nitrate.

15. The comparative study thus demonstrated the surprising and unexpected result that potassium nitrate, when blended with a dental bleaching agent in a dental bleaching composition used to bleach teeth, does not behave as a desensitizing agent at all concentrations, particularly at higher concentrations such as 3%.

16. Because potassium nitrate was known to be a desensitizing agent, and is customarily included in amounts of about 3-5% within desensitizing dental compositions, one of ordinary skill in the art, when reading U.S. Patent Nos. 5,851,512 and 5,855,870, which teach the inclusion of a

dental bleaching agent together with potassium nitrate in a single composition to both bleach and desensitize teeth in a single step, would have expected potassium nitrate to provide desensitizing properties within the standard concentration range of about 3-5%.

17. However, the comparative study, as summarized in the above-identified application, demonstrated the entirely counterintuitive and surprising result of potassium nitrate providing much greater desensitization when used within a dental bleaching composition at a concentration of only 0.5% compared to when it was included in a concentration of 3%.

18. Even more surprisingly and unexpectedly, the dental bleaching composition that included 0.5% potassium nitrate and 10.5% carbamide peroxide (composition E) also provided significantly better whitening of teeth compared to compositions that included either no potassium nitrate (composition A) or 3% potassium nitrate (compositions B-D), even better than composition B, which included 3% potassium nitrate and a higher concentration of carbamide peroxide (15%).

19. In particular, the composition that included 0.5% potassium nitrate (composition E) resulted, on average, in a total of 8.9 shade tab changes during the duration of the study, whereas the composition that included no potassium nitrate (composition A) resulted, on average, in a total of 5.4 shade tab changes, while the compositions that include 3% potassium nitrate (compositions B-D) resulted, on average, in a total of 4.6, 6.7 and 7.5 shade tab changes, respectively.

20. In summary, the comparative study demonstrated the superiority of including 0.5% potassium nitrate within a desensitizing dental bleaching composition compared to either including no potassium nitrate or 3% potassium nitrate, in terms of significantly decreased tooth sensitivity and significantly increased tooth whitening, both of which were surprising and unexpected based upon conventional knowledge at the time of the invention.

21. For example, Den-Mat, Inc. currently sells, and, on information and belief, has sold since before the filing date of the above-identified application, a dental bleaching gel that includes


a dental bleaching agent and potassium nitrate in an amount of about 5% by weight under the trade name REMBRANDT XTRA COMFORT, as indicted by an advertisement in the Dental Products Report published in November 1998.

22. In order to determine the actual concentration of potassium nitrate, a commercially available sample of REMBRANDT XTRA COMFORT was obtained and analyzed, as was a sample of Ultradent's own 0.5% potassium nitrate dental bleaching composition currently sold under the name of OPALESCENCE PF in order to confirm the accuracy of the testing method.

23. As evidenced by the analysis summarized in Exhibit A attached hereto, it was determined that REMBRANDT XTRA COMFORT includes 17% by weight carbamide peroxide and 5.17% by weight potassium nitrate, which is about 2-1/2 times greater than the upper range limit of "about 2% by weight" potassium nitrate recited in the broadest claim of the above-identified application, about 5 times greater than the upper limit of the more preferred range ("about 1% by weight"), and about 10 times greater than the most preferred amount of "about 0.5% by weight" potassium nitrate.

24. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at Salt Lake City, Utah, this 5 day of June 2001.



Dan E. Fischer, D.D.S.



II. Analyses Performed:

Samples AD 2869 were analyzed for % carbamide peroxide (CPO) using procedure TST 21.4. Samples AD 2869 were analyzed for % sodium fluoride using TST 52.4. Fluoride (F^-) content was recorded as sodium fluoride (NaF). Nitrate (NO_3) determination was done on all samples by IC using the Shimadzu system. The nitrate concentration was recorded as potassium nitrate (KNO_3). Opalescence PF 20% Melon was analyzed as a control sample. Each product was analyzed at least twice for tests performed and tests were analyzed from different syringes.

III. Results:

Product	Peroxide Results	Label Claim	Fluoride Results	Label Claim	Nitrate Results
Rembrandt (AD 2869)	17.0% (m/m) CPO	16% CPO	N/A	N/A	5.17% (m/m) KNO_3
Opalescence PF 20% Melon Batch: FKABF W/O#: W43QH	19.9% (m/m) CPO	20% CPO	0.2562% (m/m) NaF	0.11% F^- 0.25% NaF	0.48% (m/m) KNO_3 0.50% (m/m) Claim

Reviewed by: Fareed Ansari

Signature: *Fareed Ansari*

Date: 5/25/01

Analyst: Anna Lee Wilson/ Fred Williams

Signature: *Anna Lee Wilson*

Signature: *Fred Williams*

Book #: 1239 Page #: 24, 27, 28, 29

Book#: 1281 Page #: 2, 8, 15

Date: 5/25/01